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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **ORDER**

This multidistrict litigation proceeding ("MDL") involves thousands of personal injury cases related to inferior vena cava ("IVC") filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard has filed a motion to exclude the opinions of Drs. David Garcia and Michael Streiff (collectively, the "Doctors"). Doc. 7294. The motion is fully briefed, and the parties agree that oral argument is not necessary. The Court will grant the motion in part.

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. Blood clots develop in the IVC from a condition called venous thromboembolism or "VTE." IVC filters are small metal devices implanted in the IVC to catch blood clots before they reach the heart and lungs.

People at risk for VTE may be prescribed blood-thinning medications to help prevent blood clotting, but these medications do not prevent clotting for certain people at high risk for VTE and may not be an option for certain patients who could experience

thromboembolic events during surgery. In those situations, physicians may recommend implanting an IVC filter to catch any blood clots before they reach a vital organ.

IVC filters such as Bard's Simon Nitinol Filter ("SNF") originally were designed to be implanted permanently. Because some patients need only temporary filters, medical device manufacturers such as Bard developed retrievable filters. This MDL involves seven different versions of Bard retrievable filters – the Recovery, G2, G2 Express, G2X, Eclipse, Meridian, and Denali.

Each Plaintiff in this MDL was implanted with a Bard filter and claims it is defective and has caused serious injuries. Plaintiffs allege that Bard filters are more dangerous than other IVC filters because they have a higher risk of tilting, perforating the IVC, or fracturing and migrating to vital organs. Plaintiffs further allege that Bard failed to warn physicians and patients about the higher risks. Plaintiffs assert a host of state law claims, including manufacturing and design defects, failure to warn, breach of warranty, and consumer fraud and unfair trade practices. Doc. 303-1. Bard disputes Plaintiffs' allegations, contending that overall complication rates for Bard filters are comparable to those of other IVC filters and that the medical community is aware of the risks associated with IVC filters.

The Doctors are board-certified hematologists whom Plaintiffs have identified as expert witnesses. Dr. Garcia currently serves as the medical director of anti-thrombotic therapy and professor of hematology at the University of Washington. Dr. Streiff serves as the medical director of anticoagulation services and a professor of hematology at John Hopkins University. The Doctors have authored a joint expert report on physician expectations and the risks and benefits of IVC filters in the prevention and treatment of VTE. Doc. 7294-2 at 2-8.[1] They have also prepared a two-page addendum based on a review of Dr. Kessler's report. *Id.* at 9-10. Dr. Garcia has also offered opinions in the bellwether case brought by Plaintiff Doris Jones. Doc. 7299.

[1] Page citations are to the numbers placed at the top of each page by the Court's electronic filing system.

Defendants do not dispute that the Doctors have expertise in the field of clinical hematology, nor do they seek to exclude their risk-benefit opinions. Rather, Defendants ask the Court to exclude three categories of opinions: (1) opinions based on Dr. Kessler's report, (2) physician expectations and Bard's corporate conduct, and (3) Dr. Garcia's opinions in the Jones case. Doc. 7302 at 2. The Court will address each category.

II. Legal Standard.

Under Rule 702, a qualified expert may testify on the basis of "scientific, technical, or other specialized knowledge" if it "will assist the trier of fact to understand the evidence," provided the testimony rests on "sufficient facts or data" and "reliable principles and methods," and "the witness has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(a)-(d). An expert may be qualified to testify based on his or her "knowledge, skill, experience, training, or education." *Id.*

The proponent of expert testimony has the ultimate burden of showing that the expert is qualified and the proposed testimony is admissible under Rule 702. *See Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). The trial court acts as a gatekeeper to assure that expert testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993).

III. Discussion.

A. Opinions Based on Dr. Kessler's Report.

The opinions set forth in the addendum should be excluded, Defendants argue, because the Doctors merely act as conduits for Dr. Kessler's opinions without having evaluated or verified his work. Doc. 7294 at 2-4. The Court agrees.

In their report, the Doctors rely on their own clinical experiences treating patients with VTE and their research into the proper use of IVC filters to opine about physician expectations and the risks and benefits of IVC filters. Doc. 7294-2 at 5-8. Their addendum, by contrast, contains opinions unrelated to these subjects and for which the Doctors provide no methodology or foundation other than a review of Dr. Kessler's

report. *Id.* at 9-10. The Doctors opine about Bard's knowledge and intent, the company's internal testing procedures, and statistical studies purportedly showing increased risks with the Recovery and G2 filters. Specifically, the Doctors opine that:

- "Bard misled the FDA on the tendency of the Recovery filter to migrate when challenged by increased venous pressure" (*id.* at 9, ¶ 1);
- "Bard should not have marketed the [Recovery] filter since its performance was significantly poorer than the comparator, was not performing as intended, expected and represented prior to marketing and failed safety thresholds for migration" (*id.* ¶ 3);
- The Recovery "was associated with statistically significant more complications and . . . migration-related deaths" than the SNF, and "Bard knew this from an internal statistical analysis" (*id.* ¶ 4);
- "Bard knew of these deficiencies . . . but continued to market the device" (*id.* at 10, ¶ 5);
- "Bard knew that the [Recovery], G2 family and the Eclipse filters did not fulfill their own internal performance standards and would pose an increased risk . . . to patients" (*id.* ¶ 7).

Plaintiffs admit that the Doctors relied on Dr. Kessler's report for these opinions, asserting that it is not uncommon for experts to base their opinions in part on the testimony of another expert with more specialized knowledge. Doc. 7808 at 7. But the Doctors cannot merely act as conduits for Dr. Kessler's opinions about Bard's communications with the FDA and increased filter risks. *See* Doc. 9771 at 5; *In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, & Prods. Liab. Litig.*, 978 F. Supp. 2d 1053, 1066 (C.D. Cal. 2013). The addendum and deposition testimony suggest they are doing just that. They state that they read Dr. Kessler's report and formed their opinions "based upon *his* review of documents" and "[t]he data provided in *his* summary[.]" Doc. 7294-2 at 9 (emphasis added). Their opinion that Bard knew of filter defects is based on internal documents "quoted in Dr. Kessler's report[.]" *Id.* at 10, ¶ 5. And the Doctors' ultimate conclusion that Bard knew its filters did not

meet performance standards but continued to market the devices is based solely on "the cumulative data in Dr. Kessler's report." *Id.* ¶ 7.

Dr. Streiff testified that he made no effort to verify Dr. Kessler's work and instead simply took the data and findings from his report and put them in the addendum without change. Doc. 7294-3 at 15-20. Dr. Garcia testified that, other than reading the Asch study and Dr. Betensky's analysis referenced in Dr. Kessler's report, he did nothing to assess the reliability of the underlying data and documents used by Dr. Kessler. Doc. 7299-1 at 27-29. Dr. Garcia could not describe the methodology Dr. Kessler employed, and admitted that he essentially is "repeating what Kessler found[.]" *Id.* at 26. As the Court previously has held, an expert cannot simply repeat the opinions of other experts as his own when he has done nothing to verify the accuracy of the opinions. Doc. 9772 at 5; *see In re Matter of Complaint of Ingram Barge Co.*, 2016 WL 4366509, at *4 (N.D. Ill. Aug. 16, 2016).

Moreover, the Doctors have no expertise in the FDA regulatory process, corporate compliance or ethics, or the design, testing, and marketing of IVC filters. Docs. 7294-3 at 4-7, 7299-1 at 9-11. They identify no training, experience, or specialized knowledge that would enable them to opine about Bard's internal knowledge, or what Bard did or failed to do in the development of its IVC filters. Such opinions are outside the realm of their expertise and are not supported by sufficient facts and data or evaluated through reliable principles and methods. Fed. R. Evid. 702(b), (c).

The Court will exclude the opinions set forth in the Doctors' addendum. *See* Doc. 7294-2 at 9-10.

B. Physician Expectations and Corporate Conduct.

Defendants contend that the Doctors are not qualified to offer the following opinions set forth in the "Physician Expectations" section of their report: (1) "in order for physicians to make reasonable risk-benefit assessments regarding filters, it is critically important that manufacturers of IVC filters continuously apprise the clinicians who order and implant IVC filters about their safety profile, performance characteristics, design

problems, and internal risk assessments," and (2) "Bard's complete transparency about the safety profile of its IVC filters is paramount." Doc. 7294 at 5 (quoting Doc. 7294-2 at 7-8). Plaintiffs argue that the Doctors are qualified to give these opinions based on their expertise in the field of hematology and their clinical training and experience treating patients with VTE. Doc. 7808 at 4-6. The Court agrees.

Dr. Streiff's clinical practice and research focuses on the management of VTE, including the appropriate use of IVC filters. Doc. 7294-2 at 4. He regularly makes therapeutic decisions for patients with VTE, and must decide whether to manage the condition with blood-thinning medications or an IVC filter. *Id.*

Dr. Garcia has been treating patients with VTE for nearly 15 years, including patients who have suffered IVC filter failures. *Id.* at 3. He has reviewed more than 50 papers relevant to the safety and efficacy of IVC filters, and often is part of the decision-making process in which the risks and benefits of an IVC filter are weighed. *Id.*; Doc. 7808-1 at 8-13. Although he rarely recommends an IVC filter given his doubts about the benefits of implanting one, he recommended a filter last year for a patient who had suffered a traumatic brain injury and could not continue on blood-thinning medications. Doc 7808-1 at 7. He explained that this decision was made only after a long discussion with the patient about the risks and benefits of an IVC filter. *Id.* at 8.

The Court finds that the Doctors have sufficient knowledge and experience to opine about the information hematologists reasonably expect to receive from IVC filter manufacturers. *See Primiano v. Cook*, 598 F.3d 558, 566 (9th Cir. 2010) (noting that "a doctor's experience might be good reason to admit his testimony"). Defendants note that the Doctors have no expertise in implanting or removing IVC filters. Doc. 7294 at 5. But the Doctors make recommendations that patients have IVC filters implanted. Doc. 7294-2 at 3-4. And Dr. Garcia has testified that while the implanting physician must obtain informed consent for the procedure, the treating hematologist has a duty to inform the patient about the long-term risks and benefits of IVC filters. Doc. 7808-1

at 11-12. Defendants will be free to bring out on cross examination that the Doctors do not implant or remove IVC filters, but this is no basis for excluding their opinions.

Defendants contend that the opinions are nothing more than personal beliefs based solely on a review of Dr. Kessler's report. Doc. 7294 at 5. The Court does not agree. Defendants cite many pages of Dr. Garcia's deposition transcript, but identify no specific testimony showing reliance on Dr. Kessler's report for these opinions. *Id.* (citing Doc. 7299-1 at 13-20). Dr. Garcia did note that he had some concern as to whether Bard has been completely transparent in light of Dr. Kessler's report (Doc. 7299-1 at 20), but this concern is not the sole basis for his opinion that it is important for IVC filter manufacturers to disclose safety information to physicians. When asked about the basis for that opinion, Dr. Garcia explained:

> I think this is a statement that could apply to the manufacture of any device or medication that's going to be prescribed or deployed by a treating physician. . . . I think we wanted to emphasize it here because when you have an intervention – the benefit or efficacy of which is highly questionable or poorly established – ensuring that the doctors who are choosing to use it know as much detail as possible about its risks, has heightened importance.

Id. at 14.

Dr. Garcia provided a similar response when asked about the opinion that Bard's transparency regarding safety concerns is paramount:

> When you have an intervention for which the efficacy is poorly established or not established, the importance of notifying physicians about any possible risk or safety concern associated with that intervention becomes even higher than treatments, where we at least know . . . there is some well-documented benefit.

Id. at 19. Dr. Streiff testified that he and Dr. Garcia decided to offer their opinions about the importance of receiving information from IVC filter manufacturers after reviewing Dr. Kessler's report. Doc. 7294-3 at 12. But given the Doctors' vast experience treating patients with VTE, it is not clear that the report is the sole basis for their opinions.

The Court cannot conclude from the cited testimony that the opinions about physician expectations are mere personal beliefs based solely on Dr. Kessler's report. Defendants may object at trial if they believe the Doctors are simply parroting Dr. Kessler's findings, or offering an impermissible corporate conduct opinion under the guise of physician expectations. *See* Doc. 8229 at 7.

Defendants further contend that the Doctors' opinions about physician expectations are irrelevant to Plaintiffs' failure to warn claims because the relevant inquiry is whether their treating physicians were adequately warned under their respective jurisdictions. Doc. 7294 at 6. But Defendants make no effort to show that this is the relevant inquiry under the law governing the bellwether trials, or that the reasonable expectations of non-treating physicians have no probative value. The final decision on this issue must await trial.

The Court notes that some of the Doctors' opinions are couched in terms of Bard's "obligation" rather than physician expectations. Doc. 7294-2 at 7. As explained above, the Doctors are not regulatory or corporate experts, and they will not be permitted to opine on Bard's obligations. Their opinions will be limited to physician expectations.[2]

C. Dr. Garcia's Opinions in the Jones Case.

Plaintiff Jones has a fragment of an Eclipse filter lodged in her right pulmonary artery. Based in part on a review of her medical records, Dr. Garcia offers several opinions about the potential consequences of the fragment remaining in the artery. Doc. 7299. Defendants ask the Court to exclude as unreliable all of Dr. Garcia's opinions, but address only two in their motion: (1) "the presence of a foreign body in a pulmonary artery branch represents a permanent, significant risk factor for the development of in situ thrombosis," and (2) Plaintiff "should be therapeutically

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[2]Defendants argue in their reply that the Doctors' opinion that "questions remain as to whether [IVC filters] are effective" is irrelevant because the opinion says nothing about physician expectations regarding Bard filters. Doc. 8229 at 6, 8-9 (quoting Doc. 7294-2 at 7). The Court will not grant relief on an argument not made in Defendants' motion. Defendants may object if this opinion is offered and Defendants believe it to be irrelevant.

anticoagulated indefinitely." Doc. 7294 at 6-7. Defendants say nothing about Dr. Garcia's opinions that the filter fragment "can result in turbulent blood flow, which promotes local coagulation"; that "the mere presence of the filter in a pulmonary artery branch can result in a hyper-coagulable condition which promotes the creation of a local thrombus"; or that "it is likely that the filter fragment has caused injury to the inner wall of the pulmonary artery." *Id.* at 6. The Court will not exclude these opinions.

Regarding the first challenged opinion, Defendants contend that it should be excluded because Dr. Garcia reviewed no imaging of the fragment and has identified no medical literature to support his extrapolation from entire IVC filters causing thrombosis to filter fragments in other parts of the body causing thrombosis. Doc. 7294 at 7. Plaintiffs counter that the opinion is sufficiently reliable under Rule 702 and *Daubert* because it is based on Dr. Garcia's experience and training as a hematologist, the methodology he routinely employs in his clinical practice, and the generally accepted view that foreign objects in the body can promote thrombosis. Doc. 7808 at 9-12. The Court agrees.

Dr. Garcia explains in his report that "the body has a biochemical response to a foreign object exposed to circulating blood," and this response "promotes the formation of thrombosis on the foreign body (in this case, the filter fragment)." Doc. 7299 at 2. He further explained this phenomenon during his deposition:

> [A] variety of foreign objects again – and I've cited clinical examples . . . of those – when they're exposed to circulating blood, they activate factor XII, which is one of the clotting proteins that are involved in the so-called contact activation or intrinsic activation pathway. And that triggers . . . a series of chain reactions that ultimately can lead to the formation of a blood clot. And it's entirely stimulated by contact with foreign surfaces. And I have no reason to think that a filter fragment would be an exception to a rule that's certainly followed by many other foreign bodies.

Doc. 7808-1 at 31; *see id.* at 26, 29 (noting that studies show that IVC filters and other medical implants, such as catheters and heart valves, promote thrombosis).

The Court finds that Dr. Garcia has provided a sufficiently reliable basis for his

opinion that a foreign body in the pulmonary artery presents a significant risk for thrombosis. The fact that Dr. Garcia identifies no medical literature showing that IVC filter fragments can promote thrombosis does not render his opinion inadmissible. "The *Daubert* factors (peer review, publication, potential error rate, etc.) simply are not applicable to [testimony] whose reliability depends heavily on the knowledge and experience of the expert, rather than the methodology or theory behind it." *See United States v. Hankey*, 203 F.3d 1160, 1169 (9th Cir. 2000).

Defendants note that Dr. Garcia is not able to quantify the increased risk or state with certainty that the filter fragment will cause thrombosis. Doc. 7316 at 10-11. But this lack of certainty does not require exclusion of his opinion under Rule 702. The Supreme Court has explained that "it would be unreasonable to conclude that the subject of scientific testimony must be 'known' to a certainty." *Daubert*, 509 U.S. at 590; *see also Primiano*, 598 F.3d at 565 ("Lack of certainty is not, for a qualified expert, the same thing as guesswork.").[3]

Regarding the other challenged opinion – that Plaintiff should receive anticoagulation therapy indefinitely – the Court agrees with Defendants that Dr. Garcia does not know enough about Plaintiff's current health condition to give this opinion. Doc. 7294 at 6-7. The opinion is based solely on Dr. Garcia's view that Plaintiff is at risk for thrombosis due to the filter fragment. Doc. 7299 at 3. But Dr. Garcia conceded during his deposition that he cannot say whether Plaintiff is a candidate for anticoagulation therapy because he does not have enough details about her health to fully assess the risks of such therapy. Doc. 7299-1 at 33, 44. And he acknowledged that he does not even know whether Plaintiff has ever been prescribed anticoagulation therapy, either before or after the filter fragment was discovered. *Id.* at 44. In short, Dr. Garcia has no reliable basis for opining that Plaintiff should receive anticoagulation therapy indefinitely. This opinion will be excluded.

[3] Defendants further note that it is unclear which medical records Dr. Garcia reviewed. Doc. 7294 at 6. Dr. Garcia made clear during his deposition that he reviewed Plaintiff's treatment records. Doc. 7299-1 at 31.

IT IS ORDERED that Defendants' motion to exclude the opinions of Drs. David Garcia and Michael Streiff (Doc. 7294) is **granted in part and denied in part** as set forth in this order.

Dated this 12th day of February, 2018.

David G. Campbell
United States District Judge